Ask the State...

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QUESTION #1

- *What is the Department's stance on ISBT?*
- *Will it be a mandatory state requirement?*
- *Does the State have a specific timeline?*
- *Will an implementation plan be required for the next inspection round or do you have a specific timeline for implementation plans?*
- *http://www.fda.gov/cber/faq/barcodefaq.htm*

- **N.J.A.C. 8:8-8.8 (a)** Labeling shall be consistent with the most recent Code of Federal Regulations.

- **FDA Regulation:** 21 CFR 606.121(c)(13)

  The final rule entitled Bar Code Label Requirements for Human Drug Products and Biological Products was published on February 26, 2004 in the Federal Register (69 FR 9120) and the effective date for compliance is April 26, 2006.

- **AABB Standards (23rd edition):** 5.1.6.3 General Labeling Requirements

QUESTION #2

- ***What is the philosophy behind a state inspection?***
- ***Is it process oriented ie. AABB, FDA or is it a record review looking for dotted I's and crossed t's?***
- ***Will the state consider creating a checklist for the inspection like the AABB has for inspectors?***
- ***It can be used by the facilities to do internal audits. Will the state consider doing a checklist of new changes in the regulations that can be used by the facilities to highlight areas of difference?***

- **N.J.A.C. 8:8-4.1 (a)** All blood banks shall have quality control and quality assurance programs which shall be in compliance with these rules, and shall be sufficiently comprehensive to ensure that blood and blood components, reagents and equipment perform as expected.

- **N.J.A.C. 8:8-5.1 (a)** Suitable legible records prepared with indelible material shall be maintained for a period of not less than five years

- **N.J.A.C. 8:8-5.1 (b)** All corrections to errors made in the records shall not conceal the original entry; document the reason for the correction; and include the date the change was made and the initials of the person making the change.

- **N.J.A.C. 8:8-5.1 (f) 6.** Include all the significant steps of the process and who performed them;

- **FDA Regulation: 21CFR 606.160 Records**

- **AABB Standards (23rd edition): 6.0 Documents and Records**

Yes, the State will develop a checklist for inspection and will provide a list of all the significant changes in the revised Chapter 8.

QUESTION #3

- *What is the State's role in assuring an adequate blood supply during a disaster?*
- *Will the State take the lead role in planning and response or should such planning and response be done by the blood centers in conjunction with national entities like ABC, BCA, and NBE?*

- FDA
- AABB Standards – Emergency Preparedness for internal and external disasters

Interorganizational Task Force

State's Role

- Determination of health issues/risks
- Communication
- Coordination
- Encourage blood donation
- Defer elective surgery
- May waive donor collection requirements

QUESTION #4

- *What is the State's plan for avian flu virus?*
- *Will elective surgical procedures be stopped in order to lessen demand in light of declining collections within the State?*
- *Will there be strategic planning sessions now or in the near future?*

Role of NJDHSS

- **Planning and Coordination**
- **Surveillance and investigation of avian flu in New Jersey**
- **Provide guidance to Local Health Department and Local Information Network and Communication Systems (LINCS) agencies in the development of pandemic plans**
- **Provide guidance to other public health care partners regarding their roles related to an influenza pandemic communication to public**
- **May Include:**
- **Call for healthy donors to address blood shortage**
- **Request or directive to hospitals to defer elective surgery**
- **Donor deferral issues unknown at this time**
- **Quarantine under Emergency Health Power Act**

Potential Pandemic Influenza and the Impact on the Local Blood Community

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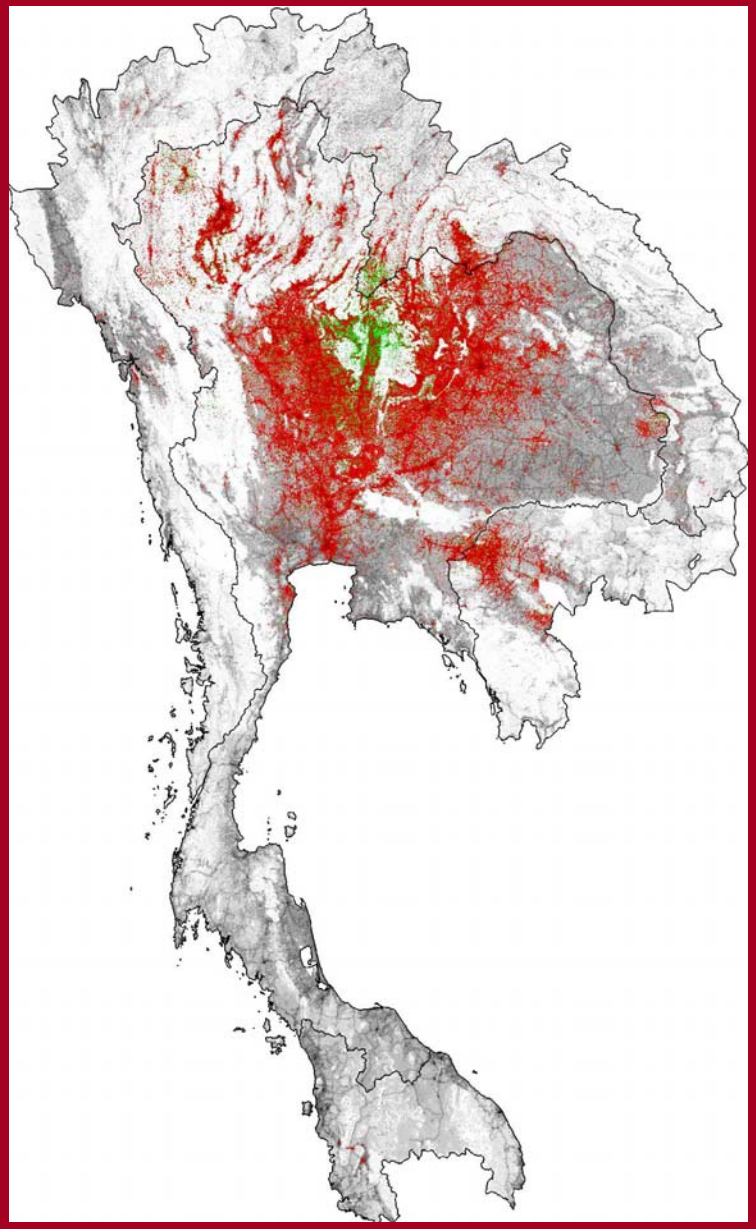
Avian Flu (H5N1)



Impact of pandemic influenza A in US

Characteristic	Moderate (1958/68)	Severe (1918)
Illness	90,000,000 (30%)	90,000,000 (30%)
Outpatient care	45,000,000	45,000,000
Admissions	865,000	9,900,000
ICU care	128,750	1,485,000
Ventilators	64,875	782,000
Deaths	200,000	1,903,000

*HHS Pandemic Influenza Plan. Nov. 2005. Estimates extrapolated from past pandemics in US. Estimates do not include potential impacts of interventions not available during 20th century.

What must be accomplish:

*"School systems, hospitals, healthcare providers, community infrastructure providers and employers should develop **plans** that identify how they will respond in the event of an influenza pandemic…. They should be **updated** periodically…. All plans should be **exercised** to identify weaknesses and promote effective implementation. Pandemic influenza response can be optimized by effectively **engaging stakeholders** during all phases…."*

HHS Pandemic Influenza Plan
Preface, page 3
November 2005

“This is a disease that spreads rapidly across the country and the idea that you can take resources from one area that’s not affected and transfer to another just doesn’t work in a pandemic.”

– Benjamin Schwartz, MD

CDC National Vaccine Program Office

ACBSA May 16, 2005

Blood is a Critical Element of the Healthcare Infrastructure

What must be accomplish?

- Blood/Plasma/Organ/Tissue and Bone Marrow Community must liaison with local, state, and federal public health.
  - Seats at the planning tables
  - Ear(s) for advocacy
  - Consistent messaging

What must be accomplish within Local and State Blood Communities?

- Bring blood/plasma/organ/tissue and bone marrow transplantation communities to the table.
  - American Red Cross is not responsible for the nation's blood supply. In many communities this may be a Community Blood Bank, Hospital Blood Bank or Regional Red Cross.
- Identify the issues that blood collection facilities and transfusion/transplantation services will likely need to consider.
- Identify options for response to those issues, and provide guidance for planning to collection facilities and transfusion/transplantation services.

Pandemic flu and the blood supply?

- Is it transfusable? Probably not
- Impact on donor base Could be awful
- Impact on operations Could be awful
  - Blood/Plasma Centers
  - Transfusion/Transplantation Services
- Impact on supply chain

Blood/Plasma/Transplantation Some Assumptions

- Donors/staff will be impacted like the general population and donations will fall
- Elective surgical needs *will* decline
- Platelet needs, e.g. to support hematologic malignancy and hematopoetic progenitor cell transplants, will not decrease
- Blood needs are unknown at Level 1 Trauma Centers, ICU settings, and patients on ventilators.

Donor Issues identified

- Willingness availability of blood/plasma donors
- Attack rates
- Absence to care for family
- Avoidance of public venues
- Immunization
- Antivirals
- FDA promulgated deferrals

Collection facility and Transfusion Transplantation Service Issues

- Attack rates
- Absence to care for family
- Education to prevent transmission
- Work rules
- Immunization
- Antivirals
- Triage of blood and component use

Communications Issues

- What is “the message”?
- How do we all agree to use “the message”
- How do we “partner” with the media to disseminate “the message”

QUESTION #5

- *With regard to transfusions, are there any regulations which define how soon after the completion of the transfusion the final set of vitals should be recorded?*
- *Does this change with a transfusion reaction and if so how?*
- *With regard to a transfusion reaction, is it acceptable to define a febrile reaction as a 2° F rise in temperature resulting in a temperature of 100° F or greater?*

This would allow a 2° rise in a post-op hypothermic patient with a warming blanket where the 2° rise to 99° F may be attributed to the blanket.

- **N.J.A.C. 8:8-4.1 (b) 10. iii.** The quality control and the quality assurance programs shall include at least the following: documented evidence of monitoring of the transfusion which shall include: The pre-transfusion, 15-minute and post-transfusion vital signs.
- **N.J.A.C. 8:8-10.2 (c) 4.** The recipient shall be observed periodically during the transfusion and for an appropriate time thereafter for potential adverse reactions. At least the pretransfusion, 15 minute, and the post transfusion vital signs shall be recorded on transfusion documentation.

- **AABB Standards (23rd edition): 5.19.6** requires that the patient's medical record include pre and post transfusion vital signs.

- **FDA Regulations: 21CFR 606.122 Instruction circular 21CFR 606.170 Adverse reaction file**

QUESTION #6

- *What are the qc requirements for a heat sealer and their frequency? Does a qc date label need to be affixed to the instrument?*

- **N.J.A.C. 8:8-4.1 (a)** All blood banks shall have quality control and quality assurance programs which shall be in compliance with these rules, and shall be sufficiently comprehensive to ensure that blood and blood components, reagents and equipment perform as expected.
- **N.J.A.C. 8:8-3.1 (c) 3** The blood bank shall identify all equipment that is critical to the provision of blood and blood components with unique identification and shall provide a schedule to ensure that all critical equipment is monitored and maintained as required by the manufacturer and in accordance with this chapter.

- **AABB Standards (23rd edition): 3.3 and 3.4**

- **FDA Regulation: PART 606_CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS Heat-sealing device** is a device intended for medical purposes that uses heat to seal plastic bags containing blood or blood components. It is found in subpart J –Products used In Establishment that Manufacture Blood and Blood Products
- **FDA Regulation: 21CFR 864.9750**

QUESTION #7

- ***Does a blood donor need to initial changes on the donor registration form in addition to the usual staff documentation?***

- **N.J.A.C. 8:8-6.3 (a)** On the day of donation the prospective donor's history shall be evaluated and the donor examined by qualified blood bank personnel trained to follow guidelines acceptable to the Department in order to determine that blood donation will not be detrimental to the donor and to determine that the donor has no evidence of disease transmissible by blood transfusion.
- **N.J.A.C. 8:8-5.1 (a)** Suitable legible records prepared with indelible material shall be maintained for a period of not less than five years.

- **FDA Regulation: 21CFR 640.3**

- **AABB Standards (23rd edition):**
  - **5.4.2 (Protection of Recipient)**
  - **5.4.3 (Protection of Donor)**

QUESTION #8

- ***In documents which require Medical Director review, is it acceptable to document the supervisor's or manager's preliminary review with initials, month and year rather than initials, month, day, and year?***

- **N.J.A.C. 8:8-5.1 (a)** Suitable legible records prepared with indelible material shall be maintained for a period of not less than five years.
- **N.J.A.C. 8:8-5.1 (b)** All corrections to errors made in the records shall not conceal the original entry; document the reason for the correction; and include the date the change was made and the initials of the person making the change.
- **N.J.A.C. 8:8-5.1 (e) 6.** Include all the significant steps of the process and who performed them
- **FDA Regulation:**

- **AABB Standards (23rd edition):**

QUESTION #9

- *New York State now allows 16 year olds to donate. Does the New Jersey Department of Health plan on following suit?*
- *What type and how many data points will be needed for the department to consider lowering the age limit?*

QUESTION #10

- ***Could the state consider the possibility of having deviations reported electronically, similar to the FDA?***